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| 10/643,674 | 08/19/2003 | Suong-Hyu Hyon | 1736-000001/REB | 5762 |
| 27572 | 7590 | 06/15/2006 | EXAMINER | |
| HARNESS, DICKEY & PIERCE, P.L.C. | | | BERMAN, SUSAN W | |
| P.O. BOX 828 | | | ART UNIT | PAPER NUMBER |
| BLOOMFIELD HILLS, MI 48303 | | | 1711 | |

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/643,674

Applicant(s)

HYON ET AL.

Examiner

Susan W. Berman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-136 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 12-136 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>11/05, 1/06, 3/06</u> . | 6) <input type="checkbox"/> Other: ____ |

Reissue Applications

This application is objected to under 37 CFR 1.172(a) as the assignee has not established its ownership interest in the patent for which reissue is being requested. An assignee must establish its ownership interest *in order to support the consent to a reissue application required by 37 CFR 1.172(a)*. The submission establishing the ownership interest of the assignee is informal. There is no indication of record that the party who signed the submission is an appropriate party to sign on behalf of the assignee. 37 CFR 3.73(b). Applicant's statement has the party who is signing stating that he is "empowered to sign this certificate". The language the party is "empowered to sign this certificate" instead of "the party is empowered to act on behalf of the assignee" is acceptable; however, **the same person who is making the statement also signing the consent form is not acceptable.**

A proper submission establishing ownership interest in the patent, pursuant to 37 CFR 1.172(a), is required in response to this action. A paper must be filed to designate Yoko Gen, C.E.O. of BMG Incorporated, as a person empowered to sign on behalf of the assignee and be signed by someone, such as the inventor or attorney, other than Yoko Gen. The papers currently filed are unacceptable because Yoko Gen is empowering himself to consent to the reissue application. It is suggested that applicant's attorney sign the statement establishing that BMG Incorporated is the Assignee and authorizing C.E.O. Yoko Gen to sign in behalf of BMG Incorporated. Then the paper "Assignee Consent under 37 C.F.R. 1.172" to filing of a reissue application can be signed by Yoko Gen as C.E.O. of BMG Incorporated.

Response to Amendment

The requested copy of the new claims submitted in this reissue application wherein the claims are underlined in their entirety has been entered.

The rejection of claims 12-136 under 35 U.S.C. 112, first paragraph, set forth in the Action mailed 05/18/2005 is withdrawn.

The rejection of claims 40-44, 52, 53, 84-88, 97-101, 111-115, 118, 128-132 and 136 under 35 U.S.C. 102(b) as being anticipated by Sun et al (5,414,049) is withdrawn.

Response to Arguments

Applicant argues that Sun et al do not disclose or suggest methods or products made by those methods wherein the UHMWPE is first crosslinked, then heated, then subjected to pressure, then cooled and then fashioned into an implant. This argument is not persuasive for the following reasons. Applicant discloses the wear factor and coefficient of friction of the disclosed products of Examples 1-8 in table 1 and compares properties of a sample that was not irradiated with a sample according to example 3 in Table 2. however, there is no comparative data to show that unexpected significantly different properties are obtained when the instantly claimed process is compared with the process taught by Sun et al. Both the instantly claimed product and the prior art product comprise UHMWPE that has been crosslinked by low dose irradiation and thermally treated. It is suggested that applicant could recite the wear factor and/or coefficient of friction obtained to further distinguish the instantly claimed product from the prior art product.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-136 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims, as written, fail to specify that the process disclosed by applicant requires irradiating raw UHMWPE with a low dose (1 to 5 MR) of radiation, followed by heating to its compression-deformation temperature and **compression-deforming** the irradiated heated UHMWPE, followed by cooling and solidifying the irradiated, compression-deformed UHMWPE while keeping the deformed state to obtain the desired product. See column 2, lines 47-55, and column 3, lines 16-20. It is suggested that the claims clearly recite the critical process steps disclosed by applicant in the product by process claims in order to clearly distinguish the instantly claimed products from those disclosed in the prior art.

With respect to claim 40, it is suggested that step (a) recite “radiation at a level of at least 1 MR to 5 MR”, that step (c) read “subjecting said heated block to pressure at its compression-deformation temperature to deform the block” and that step (d) read “cooling said block in a compression-deformed state under pressure”, as in claims 45 and 47. With respect to claim 84, it is suggested that step (a) recite “radiation at a level of at least 1 MR to 5 MR”, that step (c) read “subjecting said heated block to pressure at its compression-deformation temperature to deform the block” and that step (d) read “cooling said block in a compression-deformed state under pressure”, and that step (d) clarify what steps are used for “processing” said cooled block, as in claims 89, 91 and 99. Claim 98 fails to further limit claim 84, which already recites processing said cooled block to form said component. With respect to claim 111, it is suggested that step (a)

recite “radiation at a level of at least 1 MR to 5 MR”, that step (b) read “subjecting said crosslinked block to pressure at its compression-deformation temperature to deform the block” and that step (c) read “said block is cooled in its compression-deformed state under pressure”, as in claims 116 and 117. With respect to claim 128, it is suggested that step (a) recite “radiation at a level of at least 1 MR to 5 MR”, that step (b) read “subjecting said crosslinked block to pressure at its compression-deformation temperature to deform the block”, that step (c) read “subjecting said block to isothermal treatment in its compression-deformed state”, and that step (d) clarify what steps are used for “processing” said cooled block, as in claims 133 and 135.

Claim Rejections - 35 USC § 102/103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12-20, 23-36, 38-39, 45-51, 54-62, 66-76, 79-83, 89-95, 102-110, 116-117, 119-125 and 127 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sun et al (5,414,049). Sun et al disclose UHMWPE implants and a process for providing an implant from UHMWPE, said to usually have a molecular weight from three to six million and up to 10,000,000. Sun et al teach that irradiation in the absence of air produces crosslinking in the polymeric resin (column 2, lines 46-68). Sun et al teach process steps including melting and forming a polymeric resin into an UHMWPE raw material, machining an implant from the raw material, irradiating the packaged implant (UHMWPE raw material) at a sterilizing dose of about 2.5 Mrad, and heat treating the irradiated

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implant at temperatures from 25⁰C to 140⁰C to form crosslinks between free radicals produced upon irradiation. Isothermal treatment at temperatures from 25⁰C to 140⁰C, preferably 130⁰C for 20 hours, for annealing, is also taught. See column 1, lines 17-23, column 3, lines 36-45, column 4, lines 20-43, column 5, lines 22-67, column 6, line 42, to column 7, line 8, methods B, C and D and the Examples.

The instant product by process claims 12-20, 23-36, 38-39, 54-62, 66-76, 79-83, 102-110 and 119-125 are considered to be anticipated because Sun et al teach method steps corresponding to the recited methods for preparation of the claimed products and thus the resulting products prepared as taught by Sun et al would be expected to have the same properties as the instantly claimed products. Instant claims 12-16, 31, 32, 54-58, 66-72, 79-83, 84-88, 97-106, and 119-123 are considered to be anticipated wherein the UHMWPE has a molecular weight of about 5 million or more and is in the form of a block or a medical implant, and has been heated, subjected to pressure, cooled and crosslinked by irradiation. Sun et al specifically disclose irradiating with 2.5 Mrad, which is within the range 1 to 5 MR set forth in the instant claims.

With respect to product by process claims 14-16, 23, 26-32, 38, 39, 56-58, 69-72, 82, 83, 102-106, 110 and 119-123, Sun et al teach heating to melt and form UHMWPE before irradiation and also teach annealing the UHMWPE after irradiation. The step of melting and forming taught by Sun et al can be conducted by compression molding at the melting temperature. Sun et al also teach heating the irradiated UHMWPE molded article at temperatures from 25⁰ C to 140⁰ C to eliminate free radicals by annealing, thus disclosing temperatures within the temperature range set forth in the instant claims. Furthermore, Sun et al teach annealing at a constant temperature, such as at 130⁰ C for 20 hours.

With respect to product by process claims 17-20, 23-25, 33-36, 59-62, 73-76, 107-109, and 124-125 and process claims 45-48, 89-92, 116, 117 and 133, Sun et al teach using compression molding for melting and forming a polymeric resin in a sealed container to provide a polymeric raw material for forming a polymeric medical implant. A method of compression molding would be expected to produce deformation in a direction perpendicular to the plane of compression because it is the compression that causes the deformation. The instantly recited orientation of crystal planes in a direction parallel to the compression plane would be expected to result from the compression deformation method taught by Sun et al because the compression deformation process disclosed would be expected to produce the same results as in the instantly claimed invention, in the absence of evidence to the contrary.

With respect to method claims 49-50 and 93-94 the recited thicknesses of the UHMWPE before and after compression are considered to be properties that would be expected to be obtained by the process steps disclosed by Sun et al , in the absence of evidence to the contrary. With respect to process claims 51 and 95, the cooled article disclosed by Sun et al would be expected to have a melting point within the instantly claimed melting point wherein the starting UHMWPE materials had the same molecular weight and were treated by process steps taught by Sun et al, in the absence of evidence to the contrary . There is no evidence of record to show that the product obtained has different properties when obtained by the instantly claimed process in comparison with the process taught by Sun et al.

With respect to instant claims 12-20, 23-36, 38-39, 45-51, 89-95 and 102-110, the product by process claims recite an “ultra high molecular weight polyethylene block”, however, the “block” in the process has been deformed into a shaped component in the heating and

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application of pressure steps recited in the claims. Therefore, the product in the claims would not be expected to be in the form of a “block” and is considered to read on the implants formed by machining UHMWPE raw material in the form of a “bar stock” disclosed by Sun et al. It is recognized that Sun et al teach forming the bar stock by compression deformation and the joint component by machining; however, the product as disclosed has been formed from UHMWPE that has been crosslinked by a low dose of irradiation and thermally treated and subjected to pressure, as set forth in the instant claims. With respect to instant claims 54-62, 66-76, 79-83, 116-117, 119-125 and 127, reciting an artificial joint component, it appears that the implant disclosed by Sun et al anticipates the instantly claimed component. The reason is that Sun et al teach that the disclosed implant is formed from UHMWPE that has been crosslinked by a low dose of irradiation and thermally treated to have an acceptable level of free radicals (less than or equal to 1.0×10^{17} /g).

In product by process claims, “once a product appearing to be substantially identical is found and a 35 U.S.C. 102/103 rejection has been made, the burden shifts to the applicant to show an unobvious difference”. MPEP 2113. This rejection under 35 U.S.C. 102/103 is proper because the “patentability of a product does not depend on its method of production”. *In re Thorpe*, 227 USPQ 964, 96 (Fed. Cir. 1985). There is no comparative evidence of record to show that the different order of processing steps results in a product having different properties. Sun et al teach that the disclosed implant is formed from UHMWPE that has been crosslinked by a low dose of irradiation and thermally treated to have an acceptable level of free radicals (less than or equal to 1.0×10^{17} /g).

Claims 21, 22, 37, 49, 50, 63, 64, 77, 93 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al (5,414,049) in view of Li et al (5,037,928). See the discussion of Sun et al above. Sun et al disclose melting and forming a polymeric resin into a raw material for forming an implant, such as by compression molding, but do not mention the temperature ranges for melting and forming. Sun et al do not mention the thickness of the block or medical implant to be treated by compression molding or the thickness of the treated block or medical implant. Examples 1-3 and 5 disclose 1 mm thick UHMWPE sheets and Example 4 discloses a 0.5 inch cube, which were used as samples for determining the properties of the products disclosed. Sun et al refer to Li et al '928 for describing a heating and cooling process for preparing UHMWPE (column 3, lines 15-22). Sun et al disclose a heat treatment corresponding to instantly disclosed isothermal recrystallization wherein the temperature range is between about 25 °C and about 140 °C, preferably from 37° C to about 70° C, or the heating is for at least 48 hours at a temperature from 37° C to about 70° C and preferably for 144 hours at 50° C. Sun et al also teach that the higher the temperature the shorter the time period required for crosslinking (column 6, lines 58-61).

Li et al disclose a process for manufacturing UHMWLPE shaped articles comprising heating and cooling in an inert gas atmosphere. Li et al teach heating UHMWLPE under pressure followed by cooling under pressure and cooling while releasing the pressure without allowing remelting, including forming an UHMWLPE article either before heating or after heating and cooling (column 2, line 43, to column 3, line 20 and column 5, lines 1-5). Li et al also teach that the disclosed process is particularly useful for manufacturing articles from materials having cross-sectional dimensions of at least 1 inch by 1 inch and having temperature gradient problems

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during the cooling step and for producing articles at least 0.2 inch in thickness (column 3, lines 46-58).

It would have been obvious to one skilled in the art at the time of the invention to employ a block of UHMWPE having a thickness of more than or about 3 cm before compression and to obtain a block having a thickness of more than or about 5 mm after compression in the method disclosed by Sun et al, as taught by Li et al. Sun et al do not limit the thickness of the UHMWPE materials that can be treated as disclosed. Sun et al refer to the teaching of Li et al with regard to melting and forming UHMWPE. Li et al teach that method disclosed is particularly useful for manufacturing articles from materials having cross-sectional dimensions of at least 1 inch by 1 inch and having temperature gradient problems during the cooling step and for producing articles at least 0.2 inch in thickness (column 3, lines 46-58). Thus Li et al provide motivation to employ an UHMWPE article that can produce an article having a dimension of 0.2 inch as its smallest dimension.

Allowable Subject Matter

Claims 40, 84, 111 and 128 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Claims 41-44, 52, 53, 85-88, 97-101, 112-115, 118, 129-132 and 136 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Sun et al do not teach or suggest a method comprising irradiation of an UHMWPE block at a low dose, i.e. 1 MR to 5 MR, to crosslink the UHMWPE before employing heating and compression deformation to deform the UHMWPE block. Sun et al discloses forming an implant, such as by compression-deformation and then irradiating the formed implant to sterilize, followed by heat treatment to react any free radicals remaining in the UHMWPE.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan W. Berman whose telephone number is 571 272 1067.

The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SB
June 12, 2006


Susan W Berman
Primary Examiner
Art Unit 1711